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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,608	01/27/2004	Robert F. Rioux	03-226 US	3377

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EXAMINER

ROY, ANURADHA

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,608	Applicant(s) RIOUX ET AL.	
	Examiner Anuradha Roy	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,10,12-14,17,18 and 21-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-9,11,15,16,19,20 and 68-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment submitted on July 28, 2006.

Examiner acknowledges the amended claims in response to the first office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 11, 15, 19, 20, 68-71, & 76-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Gatto (US Patent No. 6,840,909).

Regarding claim 1, Gatto discloses a system for treating breast tissue, comprising:

a cannula (14) having at least one fluid conveying lumen (33), the cannula configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct (Abstract);

a tissue diagnostic device (12, Figure 5) slidably disposable within the at least one lumen (37); and

a tissue treatment device (50) slidably disposable within the at least one lumen (49).

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Regarding claim 7, Gatto discloses a system, further comprising a media delivery device (Column 4, lines 61-67) coupled to the at least one lumen (38).

In regards to claim 8, Gatto discloses a system, further comprising an aspirator (200) coupled to the at least one lumen (38).

Regarding claim 9, Gatto discloses a system, further comprising a tissue imaging device (12) slidably disposable within the at least one lumen (37).

In regards to claim 11, Gatto discloses a system, wherein the imaging device is capable of comprising an endoscope (12).

Regarding claim 15, Gatto discloses a system for treating breast tissue, comprising:

- a cannula (14) having a fluid conveying lumen (33), the cannula configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct (Figure 1 & Abstract);

- a tissue imaging device (12) slidably disposable within the lumen (38); and

- a tissue treatment (50) secured to, or slidably disposed within the lumen (49) of the cannula.

With regard to claim 19, Gatto discloses a media delivery device (Column 4; lines 61-67) coupled to the lumen (38).

In regards to claim 20, Gatto discloses a system, further comprising an aspirator (200) coupled to the lumen (38).

In regards to claim 68, Gatto discloses a system, wherein the tissue diagnostic device (12) and the tissue treatment device (49) are slidably disposable within the same one of the at least one lumen (33).

Regarding claim 69, Gatto discloses a system, wherein the at least one lumen (33) comprises two lumens (37 & 38).

With respect to claim 70, Gatto discloses a system, wherein the tissue treatment device (50) is slidably disposable within the lumen (49).

Regarding claim 71, Gatto discloses a system for treating breast tissue, comprising:

- a cannula (14) having a fluid conveying lumen (33), the cannula configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct (Abstract);

- a tissue diagnostic device (12) slidably disposable within the lumen (37);
- and

- a tissue treatment device (50) slidably disposable within the lumen (49).

Regarding claim 76, Gatto discloses a system further comprising a media delivery device (Column 4, lines 61-67) coupled to the lumen (38).

Regarding claim 77, Gatto discloses a system further comprising an aspirator (200) coupled to the lumen (38).

In regards to claim 78, Gatto discloses a system, further comprising a tissue

imaging device (12) slidably disposable within the lumen (37).

Regarding claim 79, Gatto discloses a system, wherein the imaging device comprises a CCD camera (Column 8, lines 8-34).

Regarding claim 80, Gatto discloses a system, wherein the imaging device comprises an endoscope (12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 72, & 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto in view of Hamm (US Patent No. 5,949,929).

Regarding claims 2 & 72, Gatto discloses a system with all of the aforementioned elements. However, Gatto does not disclose a system, wherein the tissue diagnostic device comprises a spectrometer. Hamm, however, discloses a system wherein the tissue diagnostic device comprises a spectrometer (46). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Hamm to incorporate a spectrometer with Gatto in order to analyze the spectroscopic data to determine the probability of a malignancy (Column 3, lines 45-51).

Furthermore, regarding claim 75, Gatto does not disclose an optical fiber for

delivering laser energy. However, Hamm discloses an optical fiber for delivering laser energy (101). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Hamm to incorporate an optical fiber with Gatto in order to provide optical feedback to the clinician (Column 1, lines 13-25).

Additional Claim Rejections - 35 USC § 103

Claims 4, 16, & 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto in view of Burbank et al (US Patent No. 6,497,706).

Regarding claim 4, 16, 73, & 74, Gatto discloses a system with all of the aforementioned elements. However, Gatto does not disclose a system, wherein the tissue treatment device comprises an ablation electrode, which have two electrodes in a bipolar arrangement. Burbank et al., however discloses a system, wherein the tissue treatment device comprises an ablation electrode having two electrodes in a bipolar arrangement (Column 2, lines 11-15 & Figure 2, 12 & 13). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Burbank et al. to incorporate ablation electrodes with Gatto in order to provide a means for separating and capturing a tissue specimen from the target tissue site (Column 1, line 65 - Column 2, line 4).

Response to Arguments

Applicant's arguments filed July 28, 2006 have been fully considered but they are not persuasive. Applicant asserts the imaging device and the laser fiber of Gatto is not slidably disposable with a lumen that conveys fluid. However, Examiner contends that the imaging device is slidably disposable within a lumen (37) and the laser fiber is

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slidably disposable within a lumen (49). Both of these lumens are found within the larger lumen that conveys fluid (33, lumen within 32 and 42), thus the imaging device and laser fiber are both found within a lumen that conveys fluid.

Applicant's arguments with respect to claims 1, 2, 4, 7-9, & 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

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MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is 571-272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 9:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR


MAX HINDENBURG
PATENT EXAMINER
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